Complete Summary

GUIDELINE TITLE

Guidelines for the management of severe traumatic brain injury. Intracranial pressure monitoring technology.

BIBLIOGRAPHIC SOURCE(S)

Brain Trauma Foundation, American Association of Neurological Surgeons, Congress of Neurological Surgeons. Guidelines for the management of severe traumatic brain injury. Intracranial pressure monitoring technology. J Neurotrauma 2007;24(Suppl 1):S45-S54. [41 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates previous versions: Brain Trauma Foundation, American Association of Neurological Surgeons, Congress of Neurological Surgeons, Joint Section on Neurotrauma and Critical Care. Guidelines for the management of severe traumatic brain injury: cerebral perfusion pressure. New York (NY): Brain Trauma Foundation, Inc.; 2003 Mar 14. 14 p.

Brain Trauma Foundation, Inc, American Association of Neurological Surgeons. Part 1: guidelines for the management of severe traumatic brain injury. New York (NY): Brain Trauma Foundation, Inc.; 2000. 165 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Severe traumatic brain injury

GUIDELINE CATEGORY

Technology Assessment

CLINICAL SPECIALTY

Critical Care
Emergency Medicine
Neurological Surgery
Neurology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To offer the possibility for uniformity of traumatic brain injury care, and conformity with the best standards of clinical practice.
- To evaluate different technology for intracranial pressure monitoring

TARGET POPULATION

Adults with severe traumatic brain injury (Glasgow Coma Scale score 3-8) who require intracranial pressure monitoring

INTERVENTIONS AND PRACTICES CONSIDERED

Use and placement of intracranial pressure monitoring devices:

1. Fluid-coupled external strain gauges (ventricular, subarachnoic, subdural, or epidural)
2. Fluid-coupled micro strain gauge catheter tip (ventricular)
3. Fluid-coupled fiberoptic (ventricular)
4. Pneumatic (ventricular, parenchymal, epidural)
5. Micro strain gauge (parenchymal, subdural)
6. Fiberoptic (parenchymal, subdural)

MAJOR OUTCOMES CONSIDERED

- Pressure range
- Accuracy and reliability
- Maximum error
- Cost
- Complications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

General Search Strategy

Center staff worked with a doctoral level research librarian to construct electronic search strategies for each topic (see Appendix B of the original guideline document). For new topics, the literature was searched from 1966 to 2004, and for previous topics from 1996 to 2004. Strategies with the highest likelihood of capturing most of the targeted literature were used, which resulted in the acquisition of a large proportion of non-relevant citations. Two authors were assigned to the topic, and a set of abstracts was sent to each. Blinded to each others' work, they read the abstracts and eliminated citations using the pre-determined inclusion/exclusion criteria.

Inclusion Criteria

- Human subjects
- Traumatic brain injury (TBI)
- English language
- Adults (age $\geq$18 years)
- In-hospital (e.g., no studies from the prehospital setting)
- $\geq$25 subjects
- Randomized controlled trials (RCTs), cohort studies, case-control studies, case series, databases, registries

Exclusion Criteria

- Sample contained >15% of pediatric patients or >15% of patients with pathologies other than TBI, and the data were not reported separately (see Appendix C of the original protocol document)
- Wrong independent variable (e.g., the intervention was not specific to the topic)
- Wrong dependent variable (e.g., outcomes were not mortality or morbidity, or did not associate with clinical outcomes)
- Case studies, editorials, comments, letters

Center staff compared the selections, and identified and resolved discrepancies either through consensus or through use of a third reviewer. A set of full-text publications was then sent to each author. Again blinded to each others' work, they read the publications and selected those that met the inclusion criteria.

Results of the electronic searches were supplemented by recommendations of peers and by reading reference lists of included studies. A second search was conducted from 2004 through April 2006 to capture any relevant Class I or II literature (see "Rating Scheme for the Strength of the Evidence") that might have been published since the first literature search in 2004. Relevant publications were added to those from the original search, constituting the final library of

studies that were used as evidence in this document. The yield of literature from each phase of the search is presented in Appendix D of the original guideline document.

Specific Strategy for This Topic

For this update, Medline was searched from 1996 through April of 2006 (see Appendix B of the original guideline document for search strategy), and results were supplemented with literature recommended by peers or identified from reference lists. Of 39 potentially relevant studies, 7 were added to the existing tables and used as evidence for this question (see Evidence Tables I and II in the original guideline document).

NUMBER OF SOURCE DOCUMENTS

28

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality Assessment of Diagnostic Studies

Criteria

- Screening test relevant, available, adequately described
- Study uses credible reference standard, performed regardless of test results
- Reference standard interpreted independently of screening test
- Handles indeterminate results in a reasonable manner
- Spectrum of patients included in the study
- Adequate sample size
- Administration of reliable screening test

Class of Evidence Based on Above Criteria

Class I: Evaluates relevant available screening test; uses a credible reference standard; interprets reference standard independently of screening test; reliability of test assessed; has few or handles indeterminate results in a reasonable manner; includes large number (more than 100) broad-spectrum patients with and without disease.

Class II: Evaluates relevant available screening test; uses reasonable although not best standard; interprets reference standard independent of screening test; moderate sample size (50 to 100 subjects) and with a "medium" spectrum of patients. A study may be Class II with fewer than 50 patients if it meets all of the other criteria for Class II.

Class III: Has fatal flaw such as: uses inappropriate reference standard; screening test improperly administered; biased ascertainment of reference standard; very small sample size of very narrow selected spectrum of patients.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Abstraction and Synthesis

Two authors independently abstracted data from each publication using an evidence table template (see Appendix E in the original guideline document). They compared results of their data abstraction and through consensus finalized the data tables. Due to methodological heterogeneity of studies within topics, and to the lack of literature of adequate quality, data were not combined for this topic.

Quality Assessment and Classification of Evidence for Intracranial Pressure (ICP) Monitoring Technology

Quality criteria typically used for literature about technology assessment are presented in "Rating Scheme for the Strength of the Evidence", and are derived from criteria developed by the U.S. Preventive Services Task Force. A key criterion for establishing Class I evidence for technology assessment is the application of the device in patients with and without the disease. Thus, the ability to use these criteria in evaluating intracranial pressure (ICP) monitoring technology is limited, in that it would not be ethical to test the monitors in people without probable elevated ICP. Criteria were applied when feasible to estimate the reliability of the findings from each study included for this topic; however, levels of recommendation were not applied.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In 2004, the Brain Trauma Foundation (BTF) called a meeting of all the Traumatic Brain Injury (TBI) Guidelines contributing authors for the purpose of formalizing a collaborative process of Guidelines updates, publication, and implementation shared by those with a stake in acute TBI care. A partnership of interested professional associations was formed to review, endorse and implement editions of the Guidelines. The mission of this TBI Partnership is to improve the outcome of TBI through collaboration and the promotion of evidence-based medicine.

For these and future Guidelines projects, contributing authors agreed to establish a Center for Guidelines Management (Center), which would be responsible for generating new guidelines as well as updating those that exist. The participants endorsed the BTF proposal to establish the Center to be located at Oregon Health

& Sciences University (OHSU). A collaboration was established between the Center and the Oregon Evidence-based Practice Center (EPC). The Oregon EPC conducts systematic reviews of various healthcare topics for federal and state agencies and private foundations. These reviews report the evidence from clinical research studies, and the quality of that evidence, for use by policy makers in decisions about guidelines and coverage issues. The collaboration made the expertise and personnel of the EPC available to the Center.

The TBI partnership further agreed to adopt and explicitly adhere to a systematic process and set of criteria for reviewing, assessing, and synthesizing the scientific literature. The process and criteria are derived from work by the U.S. Preventive Services Task Force, the National Health Service Centre for Reviews and Dissemination (U.K.), and the Cochrane Collaboration. The goal was to establish a process for *Guidelines* development that was scientifically rigorous, consistent across all topics, and independent of the interests and biases of contributing authors.

Authors drafted manuscripts for each topic. The entire team gathered for a 2-day work session to discuss the literature base and to achieve consensus on classification of evidence and level of recommendations. Manuscripts were revised. Virtual meetings were held with a subset of the co-authors to complete the editing and consensus processes. The final draft manuscript was circulated to the peer review panel.

Criteria were applied when feasible to estimate the reliability of the findings from each study included for this topic; however, levels of recommendation were not applied.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Estimated costs of the various intracranial pressure (ICP) devices are presented in Tables 1 and 2 of the original guideline document. The non-disposable hardware that need to be purchased with fiberoptic and strain gauge catheter tip ICP devices range in cost from $6,000 to $10,000 per bed. ICP transduction with an external strain gauge costs $208 versus an average of $545 for micro strain gauge or fiberoptic transducers.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A partnership of interested professional associations was formed to review, endorse and implement editions of the Guidelines. The mission of this Traumatic

Brain Injury (TBI) Partnership is to improve the outcome of TBI through collaboration and the promotion of evidence-based medicine.

The partnership also recommended appointing a Review Committee to consist of a small number of individuals who would serve as liaison between the guidelines development process and the key medical societies related to TBI. These representatives of neurosurgery, trauma, neurointensive care, pediatrics, emergency medicine, and prehospital care, as well as international organizations, were standing members of the Committee across all Guidelines updates. The current members of this Committee reviewed this edition of the Guidelines (the names of reviewers are listed at the front of the original guideline document).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Conclusions

In the current state of technology, the ventricular catheter connected to an external strain gauge is the most accurate, low-cost, and reliable method of monitoring intracranial pressure (ICP). It also can be recalibrated *in situ*. ICP transduction via fiberoptic or micro strain gauge devices placed in ventricular catheters provide similar benefits, but at a higher cost.

Parenchymal ICP monitors cannot be recalibrated during monitoring. Parenchymal ICP monitors, using micro strain pressure transducers, have negligible drift. The measurement drift is independent of the duration of monitoring.

Subarachnoid, subdural, and epidural monitors (fluid coupled or pneumatic) are less accurate.

Summary

In patients who receive ICP monitoring, a ventricular catheter connected to an external strain gauge transducer is the most accurate and cost effective method of monitoring ICP. Clinically significant infections or hemorrhage associated with ICP devices causing patient morbidity are rare and should not deter the decision to monitor ICP.

Parenchymal transducer devices measure ICP similar to ventricular ICP pressure but have the potential for measurement differences due to the inability to recalibrate. These devices are advantageous when ventricular ICP is not obtained or if there is obstruction in the fluid couple. Subarachnoid or subdural fluid coupled devices and epidural ICP devices are currently less accurate.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each conclusion.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate and cost effective monitoring of intracranial pressure

POTENTIAL HARMS

Intracranial pressure (ICP) monitoring complications include infection, hemorrhage, malfunction, obstruction, or malposition. While the current literature suggests these complications generally do not produce long term morbidity in patients, they can cause inaccurate ICP readings, and they can increase costs by requiring replacement of the monitor. See the original guideline document for further discussion of these complications.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The information contained in this guideline reflects the current state of knowledge at the time of publication. The Brain Trauma Foundation (BTF), American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), and other collaborating organizations are not engaged in rendering professional medical services and assume no responsibility for patient outcomes resulting from application of these general recommendations in specific patient circumstances. Accordingly, the BTF, AANS, and CNS consider adherence to these clinical practice guidelines will not necessarily assure a successful medical outcome. The information contained in these guidelines reflects published scientific evidence at the time of completion of the guidelines and cannot anticipate subsequent findings and/or additional evidence, and therefore should not be considered inclusive of all proper procedures and tests or exclusive of other procedures and tests that are reasonably directed to obtaining the same result. Medical advice and decisions are appropriately made only by a competent and licensed physician who must make decisions in light of all the facts and circumstances in each individual and particular case and on the basis of availability of resources and expertise. Guidelines are not intended to supplant physician judgment with respect to particular patients or special clinical situations and are not a substitute for physician-patient consultation. Accordingly, the BTF, AANS, and CNS consider adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's individual circumstances.
- As with the previous guidelines for traumatic brain injury, the reader must be aware of the limitations and restricted scope of the guidelines. The guidelines

reflect only what is contained in the existing human-based literature. They do not reflect pathomechanistic information from animal studies, nor *in vitro* or mathematical modeling studies.
- As in all areas of clinical medicine, the optimal plan of management for an individual patient may not fall exactly within the recommendations of these guidelines. This is because all patients, and in particular, neurotrauma patients, have heterogeneous injuries, and optimal management depends on a synthesis of the established knowledge based upon *Guidelines*, and then applied to the clinical findings in the individual patient, and refined by the clinical judgment of the treating physician.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Brain Trauma Foundation, American Association of Neurological Surgeons, Congress of Neurological Surgeons. Guidelines for the management of severe traumatic brain injury. Intracranial pressure monitoring technology. J Neurotrauma 2007;24(Suppl 1):S45-S54. [41 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 (revised 2007)

GUIDELINE DEVELOPER(S)

Brain Trauma Foundation - Disease Specific Society

SOURCE(S) OF FUNDING

Brain Trauma Foundation

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

Congress of Neurological Surgeons - Professional Association

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Brain Trauma Foundation, Inc, American Association of Neurological Surgeons. Part 1: guidelines for the management of severe traumatic brain injury. New York (NY): Brain Trauma Foundation, Inc.; 2000. 165 p.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Brain Trauma Foundation Web site.

Print copies: Available from the Brain Trauma Foundation, 708 Third Avenue, New York, NY 10017, E-mail: info@braintrauma.org

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on August 14, 2007. The information was verified by the guideline developer on January 28, 2008.

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